PIXEL technology

Declaration of Conformity EC

I, member of the Board Pixel Technology Ltd in Lodz, 1 Piękna Street, state that:

Medical Integrated System AlleRad in modules: ExPACS, Exhibeon, Exhibeon Web, Chazon, Robo, RadiBox

Is conformant with requirements of 93/42/EC Directive for medical devices in lib class (rule no 10), Act on Medical Devices (i.e. Journal of Laws 2010, No. 107, item 679), REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017, combined with executive acts and for this type of lib class device procedures indicated in Annex II (except form point 4) have been applied, in order to mark with CE label.

Reference documents (harmonized norms):

- PN-EN ISO 13485:2016 - *Medical devices - Quality management systems - Requirements for regulatory purposes*
- PN-EN ISO 14971:2019 - *Medical devices - Application of risk management to medical devices*
- PN-EN ISO 62366:2015 - *Medical devices - Application of usability engineering to medical devices*
- PN-EN ISO 62304:2010 - Medical device software – software life cycle processes
- PN-EN 1041+A1:2013-12 - *Information supplied by the manufacturer of medical devices*

Additional referece documents:

- HL7 Messaging Standard Version 2 – standard of electronic exchange of information in medical environments
- Fast Healtcare interoprepability Resources (FHIR) specification – Standard of electronic data exchange in medical environments based on the JSON format and the Representational State Transfer (REST) architecture
- Cross-Enterprise Document Sharing (XDS) profile – Profile developed and published by IHE organizations specifying the requirements for systems in terms of interoperability in data exchange (facilitates registration, distribution and access to data)The DICOM Standard 2015c – Standard of exchange and interpretation of medical data representing or associated with diagnostic images in medicine
- PN-EN ISO 15223-1:2016 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part I: General requirements

Characteristics of the device:

Medical Integrated System AlleRad is a software to be used in individuals to diagnose run of disease, effects of injuries or handicap as well as to examine anatomical structure or physiological processes. It allows for registration, storing, sharing, sending and exchange of data between medical systems in DICOM 3.0, HL7 standards. It allows displaying of radiology studies and discloses set of mechanisms and tools enabling making diagnosis.

Code and generic name according to UMDNS	26-869 Picture Archiving and Communication System Information System Software
Number of EC certificate of conformance	Certyfikat WE nr. 1434-MDD-454/2019
Address and identification number of a notified body	Polskie Centrum Badań i Certyfikacji Ul. Puławska 469, 02-844 Warszawa Jednostka notyfikowana nr 1434

I declare with full responsibility that medical device fulfills requirements indicated in the aforementioned reference documents on the condition of its use in accordance with destiny, binding norms and technical recommendations.

Łódź 06.10.2021

Jakub Musiałek

CZŁONEK ZARZĄDU
Jakub Musiałek

PIXEL TECHNOLOGY Sp. z o.o.
93-558 Łódź, ul. Piękna 1
NIP 7271010965 REG.471043763